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Paper 151
Filed: 17 December 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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MARK DOUGLAS **HOWELL**,
CHERYL LYNN, and LELAND CHARLES LEBER
Junior Party
(Patent 6,379,708),

v.

M. RIGDON **LENTZ**
Senior Party
(Application 09/709,045).

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Patent Interference No. 105,413 (SGL)
(Technology Center 1600)

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Oral Hearing Held: November 20, 2007

Before RICHARD TORCZON, SALLY G. LANE, and MICHAEL P. TIERNEY, *Administrative Patent Judges.*

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The above-entitled matter came on for hearing on Tuesday, November 20, 2007, commencing at 10:02 a.m., at The U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Deborah Rinaldo, RPR, Notary Public.

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PROCEEDINGS

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JUDGE LANE: We're here in Interference 105413, Howell versus Lentz. Can I find out who I have here for Junior Party Howell?

MR. HUNTINGTON: Good morning, Your Honor. I'm Danny Huntington and I have here with me Mark Howell, who is the Howell of Howell versus Lentz. And I also have Bill Hughet, who is here observing. He's one of the members of my firm.

JUDGE LANE: And for Senior Party Lentz?

MS. CAHOON: Susan Cahoon here. And we'll be arguing on behalf of Senior Party Lentz. With me is Patrea Pabst and Dr. Charlie Vorndran, who is with Ms. Pabst's firm.

JUDGE LANE: Thank you. So we'll start with Junior Party. Each side has 20 minutes and Junior Party may reserve some time for rebuttal if you wish.

MR. HUNTINGTON: Thank you, Your Honor. I would like to reserve five minutes. But I want to start actually by bringing to the attention of the Board what I consider a serious breach of an order of this Board.

It's been quite a while ago but you may remember that back at the start of this case in March of 2006 we filed a list of proposed motions. And one those proposed motions, number 18, was a contingent miscellaneous motion to bring in application 09/699003 and have it designated as corresponding to the count.

We indicated, of course, if it remained suspended, which it was at the time, then we had no issue with that. It would be okay not to bring it in.

You then ordered on March 29, 2006, that the motion is not authorized at this time but Lentz should immediately notify the Board if it becomes aware of the prosecution and that application is no longer suspended.

We discovered this morning that not only has prosecution been going on essentially the entire time since that order was issued, but there is a notice of allowance and issue fee due that was issued at the beginning of this month.

Now, we think that we're seriously prejudiced by that because we didn't get a chance to file the motion. And moreover, they didn't tell you that the prosecution had continued on.

And in fact, about a month ago they filed a massive number of documents, all the documents that have been cited in this case in that prosecution file before the notice of allowance.

So frankly, I think the way to deal with this would be to simply suspend that case right now, not have it issue as a sanction and simply just have it wait until this interference is over, including any 146 appeal.

So I just bring that to your attention for you to look at. But frankly, the order couldn't be clearer that they should have told you about this.

JUDGE LANE: Where it is right now, Mr. Huntington, there is a notice of allowance and an issue fee is due, but has not been paid yet?

MR. HUNTINGTON: Correct.

JUDGE LANE: Could you tell from the record that the examiner was aware of the interference?

MR. HUNTINGTON: The examiner is aware. What happened is, the order came out in March. In June there was a new final rejection.

That was responded to in September of 2006. Then there was a notice of appeal in December 2006 and then another suspension based on a possible interference in February of 2007.

And then there was this IDS file, the suspension -- the notice of allowance says the suspension has expired, so I'm allowing this case.

And as a part of filing the documents, they did say these were filed in this interference. So the examiner is aware of the interference, but I don't think, at least from what I could see -- there is a massive amount of paper and I only found out about it this morning. But I don't see that they have ever told the examiner that they were supposed to inform the Board.

So that's my concern. And I leave it to you to decide what to be done. But obviously we're very upset about this.

MS. PABST: May I respond to that?

JUDGE LANE: Yes, when you take your turn, yes.

MR. HUNTINGTON: Now, turning to the issues that we're here for today, basically what we are arguing, the party Howell is entitled to judgment here because we were the first to conceive and then we were diligent until a constructive reduction to practice.

There are two components to that, that conception. The first is a '94 document which was part of the conception but not a complete conception. And then later there were experiments in late '96 and early '97 which provided the rest of the information to allow a conception to occur.

We are not talking about a partial conception at one time. We're simply saying that this was a process, providing history of it. And the conception occurred in early '97 when the experiments that are reported in the Selinsky paper, which is Howell Exhibit 2015, when those experiments were done.

Now, a copy of that manuscript, as we've talked about before, was sent to Dr. Lentz before it was published. It's our contention that the reason that Dr. Lentz came up with this invention is because he received that document. I'm going to talk more about that.

But the first thing, I think, that to put this in context, we need to talk about what the significance of the Selinsky paper is because there is obviously a lot of discussion about that.

In the first place, both of the parties had that paper used in rejecting their claims during the prosecution. Both of them overcame it.

In the case of Lentz they swore behind that paper and put in the same documents that you've seen in their initial brief here as a part of overcoming that. They never told the examiner that Lentz had gotten this paper earlier. They simply just looked at the publication date and said, We can beat the publication date.

JUDGE LANE: What evidence do you have that Dr. Lentz received the Selinsky paper?

MR. HUNTINGTON: Well, we have the evidence that Howell says he sent it. We asked for the testimony of Jennifer Lentz, and that testimony -- the request to take her deposition was denied.

JUDGE LANE: But you agree that what's in the Selinsky paper is not a complete conception?

MR. HUNTINGTON: It's not a complete conception. But what it does is it provides additional information over and above what was previously in the prior art. What was in the prior art previously was these Lentz ultrafiltration experiments and work that had been done.

So you see that if you take numerous compounds, on the order of hundreds, perhaps thousands by using a filter with a certain size of port,

that you remove a whole bunch of compounds and that allows TNF to more effectively attack the tumor.

Now, there was two papers, actually, back in the early 1990s. They are in the record here as 1125 and 1126. One of them is the Gatanaga paper and the other one is the Shawl paper.

And what those showed was experiments back at that time where they took TNF, they attached it to a support, they then ran plasma through it, and what attached to that, they then sequenced that material. It attached the TNF and decided that that was the TNF receptor, a soluble TNF receptor. And they said that that was perhaps the inhibitor.

Now, that's where the art stood until you came along with the Selinsky paper. Because until that time, yes, there were some thoughts that maybe that was it, but there wasn't anything to single it down and say that single material by itself could have an effect.

What the Selinsky experiments were were specific experiments to look at just soluble TNF factor itself. But they were not taking the soluble TNF factor, the receptor, and using it -- or removing it, I should say, removing it to show that TNF could attack a tumor. It was the flip side of that. It was showing that if you made tumors more susceptible to TNF, then it would have an effect.

So it shows that the soluble TNF receptor is an inhibitor or at least it implies that it is. It doesn't really show that it's preventing the action. But it shows that that material by itself is an effective agent on these tumors and involved in the tumor and perhaps a suppression, but it doesn't show what the count is, what the count is, is inhibiting.

So it's a piece of information. It's a very important piece of information, but it's not enough by itself to make the count obvious. That's

why I'm not talking about derivation.

But on the other hand, it is material information. And there is no question about that, that it's material information. And I understand that the question of what's material information may not be relevant until we get -- if we get to inequitable conduct in other stages of these proceedings should we not be successful here. But that's the context of this.

And in fact, talking about Selinsky and about this Shawl and Gatanaga papers, one way of looking at this is maybe it's unpatentable to everybody. You could look at it and say Lentz had the paper before he filed and so it's prior art to him. And Howell didn't file within a year after it was published. So it's prior art to Howell.

So maybe it's not patentable to anybody. But as I said, I don't think that the Selinsky paper by itself makes the invention unpatentable and that's what the examiner ultimately found. It was stated to be an invitation to experiment.

Now, I want to go back to the end of 1997. This is back at a time before Lentz had -- says he made the invention. Because remember they say that the invention is April 20, 1998, with this draft patent application a month before they filed.

As a part of trying to raise capital, Dr. Lentz is put into touch with Patrea Pabst to prepare a patent application. He meets with her. She prepares that patent application. She sends it to him on April 20th of 1998. And that application doesn't contain the information about the count. There is no allegation that it does at the time she sends it to him.

He then makes revisions and puts that in. So it's only when he was reviewing that application that he first put the idea in. And apparently he didn't tell her that the reason that he came up with that idea was because

of the Selinsky paper.

Now, while I've talked a little bit about what's in the Lentz priority reply, I want to talk about a little bit more before I discuss more the Howell's priority case.

That is because there are a host of new arguments and evidence that appear the first time in the Lentz reply that it's new Lentz Exhibits 1126 through 1133.

Frankly, we feel like they were sandbagging us. Now, remember the sequence of events. We file our priority case. We put all of our evidence in. They then cross-examine our inventors. Then they put in their priority case. And then both sides file oppositions.

In their priority case, they have a one-page priority motion. I've never seen such a short priority motion. But that's all it is. And then there is a declaration. One declaration, a couple of exhibits about this application, that's it. The entire thing.

Even though they knew that in our paper we were saying that the Selinsky paper had been given to Dr. Lentz back in February, two months before this April application was filed.

JUDGE TORCZON: Mr. Huntington, let me interject here. The fact that they have got a short priority motion may be a sign of confidence, and what's almost bolstering that here is the fact that you are talking about their case when this is your time to talk about your priority case.

I mean, are we avoiding your priority case because you don't have one or are we eventually going to get to this? Because you are giving your opposition before they have even stated their case in the argument.

MR. HUNTINGTON: Well, I believe that the fact that they

spent so much time shoring it up in their reply shows why their original case isn't any good. If you want me to turn to our case, I will.

JUDGE TORCZON: I think that's where we need to start. You are the junior party. You have got the burden. If you don't have a case at all, they could have done the worst job in the world and it doesn't matter. So give me a reason to care about whether they have a case.

MR. HUNTINGTON: As long as you are going to say that they are limited to an April 20, 1998 priority date.

JUDGE TORCZON: I'm not saying anything. I'm saying I want to hear your case before I start worrying about their case.

MR. HUNTINGTON: Where I have to show conception depends upon what their case is going to be. We thought when we filed our opposition that they were saying April 20th of 1998. Then we get their reply and they are saying, We invented it back in '96 and 97.

That's the point I'm getting to. I think it's unfair that they should be able to throw that out in the reply and that's why we should strike that.

But moving to our case, what we have is a continuous set of experiments from the time of early 1997 when the conception goes by Dr. Selinsky. She was a graduate student at that time and she worked throughout that entire period on soluble TNF receptors alone.

JUDGE LANE: Mr. Huntington, I think maybe now in the interest of time, maybe you want to address more your diligence. Lentz has alleged that you have 144 business days with no activity or nothing that you allege to be excusable delay beginning at April 20th of 1998. Can you explain? That does seem like a lot.

MR. HUNTINGTON: Well, there are several different parts of

it. The first is notice that they say April 1st, even though they only have April 20th. I get 19 days right off the top.

JUDGE LANE: Well, you are right, it does say from April 1st.

MR. HUNTINGTON: So April 19th is a date we have to talk about. Not April 1st. So that takes care of part of it.

JUDGE LANE: Is April 1st through April 19th a period of inactivity? Are those 19 days --

MR. HUNTINGTON: No. We have activity during those days, as I recall. I didn't look at that specifically.

JUDGE TIERNEY: Let's start with April 19th.

MR. HUNTINGTON: Starting with April 19th, Dr. Selinsky was a graduate student. It was her job. And essentially her job was to do these experiments as well as to get her Ph.D. So the times when she was not active relate to the death of her father, relate to her preparing her Ph.D. thesis, to preparing a publication that was part of her Ph.D. thesis and vacations.

I don't think when you look at it in the overall context that there are that many days. It's just a number. What you need to look at is when were those times? When you look at those times, you'll see that they are around holidays or vacations.

JUDGE LANE: There are three listed inventors. Why could we only count on Ms. Selinsky to do work? Why weren't the other inventors pitching in?

MR. HUNTINGTON: Well, that's not an issue that was raised by the other side. So I don't have the case at hand, but there is a case that says when one of the -- simply showing one of them. You don't have to show that all three were unavailable.

I would be pleased to provide that after the hearing if you would like. But we're not required by law -- by precedent to show what the other inventors were doing or not doing.

Dr. Leber provided something that had nothing to do with this particular diligence. In other words, when you get from the time that you think that soluble TNF receptor is the molecule that you need to go after, then the next step is demonstrating that in an experiment.

To demonstrate that, you need to have antibodies to do that. This was directed to making those antibodies. That actually leads me to one of the attacks that they make on this saying you could have gone out and purchased the antibodies.

That doesn't make any sense. And the reason it doesn't is because if you are going to try to use an extra corporeal column to treat a mouse, that's just silly.

The current systems require 250 to 300 milliliters of blood to circulate outside of the body in the column during the treatment. The entire blood volume of a mouse is 3 or 4 milliliters. It's just an impossible thing.

JUDGE LANE: What about this -- I'm looking at your appendix 2, this delay, for instance, between Tuesday, November 24, 1998, and it goes all the way through, looks like, January 12th. I mean, there is one entry as January 4th.

I realize there is Christmas and Thanksgiving, but nonetheless, it doesn't say "vacation." There is nothing. I don't understand what happened during those days. It seems like a very long vacation.

MR. HUNTINGTON: Well, part of it was a very long vacation. You also have to understand that Dr. Selinsky was the oldest child and this was the first Christmas after her father passed away. So she was

gone during that time. I apologize for the fact that the chart doesn't say "vacation," but that is what that time was.

JUDGE TIERNEY: Looking at Lentz's opposition to Howell's priority motion, looking on pages 13 to 14, and it appears they've raised an issue of asking why no one else in Howell's laboratory was able to work on the project while Dr. Selinsky was busy with vacations, the dissertation.

MR. HUNTINGTON: You are talking about in the revised opposition? Is that where you are, or in the reply?

JUDGE TIERNEY: I'm in the Lentz opposition to Howell party motion.

MR. HUNTINGTON: Which page?

JUDGE TIERNEY: Go to page 14, please. I would like you to address their arguments regarding why no one else in Dr. Howell's laboratory was able to help out Dr. Selinsky when she was busy on other projects.

MR. HUNTINGTON: I think we addressed that -- well, why don't we do this. Rather than me sitting here and looking at it, as a part of my rebuttal, I'll look for that and see if I can address that. I will come back to it and answer the question.

JUDGE LANE: Mr. Huntington, one other question while we're still on diligence. I was looking and I just want to make sure that I understand what your corroboration of the diligence is. And I think you have, for instance, a couple declarations like this, but one is from Karen Boroughs.

And she says that she reviewed the entries for Dr. Selinsky in the diligence table and says she's familiar with the experiments and can attest to the fact that these experiments were, in fact, performed by Dr.

Selinsky on or about the dates recited in the declaration.

Is that the totality of the corroborations? Anything else we should look at?

MR. HUNTINGTON: There is not a day-by-day sign-off as you would normally look. I think that's your question.

JUDGE LANE: And then Dr. Selinsky's notebooks, were they witnessed?

MR. HUNTINGTON: I don't believe they were witnessed. But understand that Dr. Selinsky, while she's a named inventor on the application, she is not a person that we say is an inventor of the invention. She is a corroborator because she didn't invent the count in this interference. And we made that clear.

So that's why I think hers doesn't have to be countersigned, because she's not an inventor of the count here.

Why don't I at this point --

JUDGE LANE: Maybe take a minute or two. You are almost out of time if you want to save some for your rebuttal.

MR. HUNTINGTON: If I've answered your questions, I'm going to sit and then I'll wait -- I think most of the rest of the things I want to say relate to their case rather than my case.

JUDGE LANE: Thank you.

Ms. Cahoon -- and you may want to start addressing this application 699003. I don't know if Ms. Pabst --

MS. CAHOON: I think Ms. Pabst is involved in that and needs to explain the status of that to you.

MS. PABST: We filed in October, before the proposed change in law, a huge number of information disclosure statements making sure that

everything was cited and everything, just because we thought there was going to be a change in the law.

And this was one of those cases where we filed a lot, I guess. We had no expectation that the examiner was going to issue a notice of allowance. I haven't actually seen the package. I don't know whether the IDS was entered, considered or anything else about it. So I'm not in a position to comment on anything about this notice of allowance.

JUDGE LANE: When did you get the notice of allowance?

MS. PABST: I don't know, to be perfectly honest.

JUDGE LANE: Do you remember getting it?

MS. PABST: I know that something came in and we were trying to find out from the examiner what was going on. There is no question that the examiner knows about this interference. We tried to provoke with copying of claims in that case.

JUDGE LANE: Wasn't there an order in the case that said you were to inform the Board whenever prosecution was no longer suspended?

MS. PABST: It's very recent, I know that. It's been since we filed an information disclosure statement which was done at the end of October. So it's been in the last -- it's very recent. That, again, I don't know.

We have a call in to the examiner to find out what's going on. We had -- the examiner knew about this interference, the examiner I spoke to before when it was suspended and asked her if she had talked about the case with the Board and she assured me that she had contacted the Board.

So I have contacted her to find out what's going on because, to be honest, I don't know.

JUDGE LANE: Why didn't you do as the order said and let me know as soon as the prosecution was no longer suspended?

MS. PABST: Because I don't know what's going on in the case. We got a notice, but I'm trying to find out whether it was sent in error, whether the information disclosure statement was, in fact, considered. I don't know what's going on with this case. It's been in the last couple of weeks.

JUDGE LANE: But you recall getting a notice of allowance and you did not call the Board?

MS. PABST: No, we did not. We were trying to find out if it was sent in error, because if it was sent in error, then there would be no reason to contact the Board because the examiner would have withdrawn it.

She had told me before that she had spoken with the Board about this case and was following directions from the Board. So, again, that's where it stood right there.

JUDGE TORCZON: There is an appeal in this case?

MS. PABST: No, there is no appeal. The case was allowed and we had tried to bring it into the interference and the examiner suspended prosecution because this interference was pending.

Then we saw no action. It has been suspended ever since. Within the last couple of weeks we -- the end of October we filed an information disclosure statement. Yes, it was suspended. We still filed the IDS.

That was the first thing that had occurred in this case since it was suspended. And we've filed IDSes in every case. When we were trying to find out what was going on with the case because the examiner was well aware of the interference, the examiner had said she had talked to the Board about this case --

JUDGE LANE: Who was the examiner?

MS. PABST: I don't remember her name at the moment. I'm sorry. I don't have any of the documents relating to it. I don't know what's going on. I don't know the date of that. I know it came in and I don't know what's going on with it.

I know we're trying to find out whether this was sent in error, whether she -- she had told me before that she was in communication with the Board directly on this case. So this is very recent and I don't know what's going on.

JUDGE TORCZON: You understand, though, that this needs to get resolved before it passes to issue?

MS. PABST: We haven't paid the issue fee. Nothing has happened. It hasn't even been reported to the client.

JUDGE TORCZON: I understand that. I'm not saying you paid it. I'm saying that you are in a real time bind now because if you don't pay the issue fee, it goes abandoned.

MS. PABST: It's very recent.

JUDGE TORCZON: I'm just trying to impress on you that you have a very narrow window to get this resolved.

MS. PABST: I'm aware of that. But maybe I can find the examiner today and say, I really need an answer on this.

But I knew we had the hearing today and I didn't -- I don't know the status. I do know without any doubt that this examiner is well aware of this interference.

She suspended it in view of this interference with full knowledge. She told me when I talked to her that she had been in communication with the Board about this interference.

So there was no expectation on my part that -- I guess I have to

be honest. I made an assumption, which probably was a wrong one, that she had notified you all as well.

But it's very recent. It has not been reported to the client. I don't know if they considered this IDS. I don't know and we're trying to find out.

MS. CAHOON: Your Honor, I think the answer is that Ms. Pabst today will attempt to contact the examiner, advise her of the suspension and the prior order of the Board.

MS. PABST: Well, she knew about all that.

MS. CAHOON: Well, she might have forgotten it. That's the issue. We need to re-alert her to this and determine if this was issued in error. If it wasn't an error and it's been done, then we need to get it suspended so we're not up against the tight time deadline on the filing -- the payment.

MS. PABST: I'm a little surprised that she didn't clear this with the Board. She told me she had talked with you all the whole way about it.

JUDGE LANE: At any rate, I think there was an order in place that you needed to comply with and did not, regardless of what the examiner may have told you.

MS. PABST: No. And, I mean, if she issued it in error, I expected her to withdraw it.

JUDGE LANE: All right. Thank you.

MS. CAHOON: Let me just briefly address the Lentz priority motion. As the panel can see, it covers a very limited period of time. It's essentially the swearing-behind time period that was done during the prosecution to make clear that Lentz was possessed of his invention prior to the actual publication of the Selinsky paper.

The Selinsky paper, there are a couple of different dates floating around, but it appears to have been published either a few days before the date which recorded benefit or a few days after. April 20th takes it before that.

It was a very short, direct paper on that which covered the activities of patent counsel, the diligence with which they moved from April 20th to May 22nd when the actual filing occurred.

What was given in response to that was what I found to be the most fulsome -- I hesitate to use pejorative terms, but sometimes they do come to mind -- diatribe against Dr. Lentz and his integrity and the notion that somehow he was stealing from Dr. Howell and wouldn't have filed this kind of patent application at all but for his alleged receipt of an advanced copy of the paper from Dr. Selinsky.

And it was in that context with all of the arguments being made in response to our motion that we then responded with additional information and evidence. It was not designed to suggest that there was an actual invention as of '96 or '97. But rather it was intended to put into context the events that culminated in Dr. Lentz's bringing a new patent application forward in early 1998.

That's why we showed you, and you find it in Lentz Exhibit 1118, that Dr. Lentz in 1996 and 1997 was working further with human patients in the clinic, cancer victims. He was refining his techniques and showing through additional types of experimentation a direct correlation between the effects on levels of soluble receptor for TNF and the inflammatory response.

JUDGE LANE: Let me just stop you and back you up a minute. Just so we have this straight, are you relying on April 20, 1998, as

your conception date? I'm trying to figure out, are you really just relying upon your constructive reduction to practice date?

MS. CAHOON: Your Honor, our basic position is that this is the kind of invention that you really can't have a conception that's independent of a reduction to practice because of some of the uncertainties about cancer treatment. It really is in that narrow band in the life sciences where you have a simultaneous conception and reduction.

But if this panel were to say it is possible to have a conception independent of an actual reduction to practice, then that April 20th document shows that type of conception because it's the same thing found in the later accorded benefit May 22nd patent application.

JUDGE LANE: So that would be your alleged conception date. And then you allege a -- then you have the constructive reduction to practice of May of '98, May 22nd. And then you say you had diligence.

MS. CAHOON: The diligence from April 20, 1998. 32 days of diligence is all we're talking about. That's what Ms. Pabst's short declaration addressed with the receipt of the applications, the communications back and forth --

JUDGE LANE: Now, in your priority statement, didn't your priority statement say you are not relying on diligence?

MS. CAHOON: The original priority statements, if we go back historically, was at a time when an issue was floating around and the possible consideration was given to arguing that as early as 1990, Dr. Lentz -- and we've shown the documents where he was talking to people about having selective removal, not having the filtration system, but going to antibodies on a column to remove the appropriately identified -- but they didn't know yet what they would be for sure, the appropriate receptors.

We know we couldn't show diligence from 1990. We abandoned that effort. The only diligence showing we're now talking about is looking back 32 days ahead of the actual filing.

JUDGE LANE: Did you file another priority statement?

MS. CAHOON: We just filed this motion, Your Honor.

JUDGE TIERNEY: For purposes of reviewing Howell's priority motion, them being junior party, does it make any difference whether or not we give you a May 22, 1998 date?

MS. CAHOON: I don't think it ultimately does because we've already addressed and dealt with the Selinsky paper and prosecution.

But what this became was a vehicle which Howell used to inject still more arguments about did Dr. Lentz somehow decide to go get a patent because he had seen this advanced article and this sort of indirect inequitable conduct argument that keeps creeping in to virtually every time we have papers before this Board or before Judge Lane.

And that was the context in which in our response, in the Lentz reply in support of the motion, we did show, wait a minute, Dr. Lentz was working, he was correlating, he was targeting in on soluble receptor as the critical element to address in the treatment and provoking the inflammatory response through work with human patients in '96 and '97.

He was talking to his advisors -- financial advisors in '97 about the need to try to go find a column that could selectively remove. They started to look to see if they were commercially available columns.

We see all of that happening versus the story that Howell would have the Board follow, that Dr. Lentz was just sitting around, had no thoughts of new patenting and somehow this critical information came out of the Selinsky paper.

The other thing that we have addressed and I think tried to point out and debunk is the alleged criticality of the Selinsky paper. The Selinsky paper itself says it is simply a confirmation of approaches that others had used.

It used its own particular method not to show that there were no other cytokine receptors that might influence the inflammatory response, but just to study TNF and soluble receptor to TNF in a special murine cell line where you had a cell line that was very sensitive to TNF and you ran these tests to confirm, yes, TNF plays a role in cell lysis, and soluble receptor affects whether or not you get the lysis effects that TNN [sic] seems to contribute to under any of the three cytotoxicity mechanisms.

There is nothing in the article that says this is the only cytokine that does that. That's something that I find in the papers but not in the article itself.

Dr. Wigzel's declaration confirmed that this was simply consistent with the literature that was out there. It used a different method of getting to the same conclusion that perhaps others had, but it wasn't teaching anything dramatically new.

And it clearly was something that was only consistent with Dr. Lentz's long-formed belief that there was something very important about addressing soluble TNFR and that that was what he was measuring and correlating in the human patient studies in '96 and '97.

So even if he got this article, it was not a material element. We agree with the statements that Selinsky, et al., made in the original prosecution when this reference was brought up against their patent. They said it was at best an invitation to experiment. It doesn't really disclose anything critical.

Yet now it suddenly becomes both a key component in the alleged conception of the Howell invention and something without which somehow Dr. Lentz would have been clueless that he wanted to look at selective removal of certain cytokines and in particular soluble receptor to the TNF cytokine.

We think that just doesn't hang together when you look at the information. And Dr. Howell, et al., really didn't carry the burden of proving any actual receipt.

They don't have a letter transmitting the article. They don't have any phone records that they presented showing the alleged phone calls. And at the end of the day, it's really much ado about nothing in the ultimate issues before this panel.

Now, as to Howell's motion --

JUDGE TORCZON: Before you move on, I would like to explore the idea of unpredictability in this art because I'm getting two different senses from you.

My understanding from what you said earlier is that it's Lentz's position that because of the unpredictability in the art, you really couldn't have a conception separate from a reduction to practice. So we're talking about an actual reduction to practice.

MS. CAHOON: Or if you don't do that, you get the benefit of the constructive reduction by filing your application.

JUDGE TORCZON: I guess I see a problem there, though. And that is, if it's really that unpredictable, I don't see how a constructive reduction could be good enough. I mean, if you need the actual reduction to know you've got something, then a constructive, by definition, you don't know.

MS. CAHOON: Well, that is true and I can't disagree with Your Honor on that one. The case law does give the benefit to the person who decides that they are willing to go forward with the constructive reduction by the filing of a patent application and treat that as a valid application. They may have issues as to whether they have fully enabled. They may have a lot of things that arise --

JUDGE TORCZON: Counsel, when you file it, aren't you telling us that it's fully enabled?

MS. CAHOON: Well, yes.

JUDGE TORCZON: So it's not that I have a problem with either position. I guess I just need Lentz to choose. I mean, was it enabled when they filed or was it not enabled until they have an actual reduction to practice?

MS. CAHOON: We believe that it was enabled when it was filed and that the Board's findings that give us the benefit of the May 22, '98 date have already addressed and looked at those challenges to the original patents and to the patent application in the interference.

JUDGE TORCZON: So then Lentz's position based on that has to be that you don't need an actual reduction to practice in order to have a conception here.

Forget what the case law could permit you to do. On these facts, it seems to me that if you are going with the date of your constructive reduction to practice, you can't hold out for an actual reduction to practice because to do that you would have to be telling us you weren't enabled when you filed.

MS. CAHOON: And we're clearly not telling you that, Your Honor. But we are saying that, rightly or wrongly, there is a clear line of

cases that in that sort of conundrum have accepted the validity of patents in the life sciences --

JUDGE TORCZON: But not on these facts. On these facts it seems to me you have got to choose. The cases don't say that -- what you are calling the narrow instance where conception and reduction to practice have to be simultaneous, can you point me to a single case where a constructive reduction to practice was accepted?

I think there are two different lines of cases and we're conflating the two.

MS. CAHOON: Well, I think in our brief when we addressed that line of cases in the context of this and other motions that we did cite such a case. I would have to go double-check now on it.

But at the end of the day, for purposes of most of this argument, you almost don't have to decide that issue. We clearly have a date that's well ahead of whether you say it's the 22nd of May or the 20th of April, and the real question in all of this is Howell's diligence.

And you don't have to ultimately reach that issue, because if you give them the benefit, which they say they are entitled to, of stringing together what Dr. Howell did back in '93, '94 with these research proposals and the experiments in late '96 that were ultimately the subject of the Selinsky paper and call that a valid conception, then the issue of diligence in reducing it to practice is where we think they come completely improper and have failed to make their fundamental showing and carry their burden.

We looked and the case law talks about near the date. We said, If you give us April 20, then let's look starting around the first of April. In fact, the early days in April were days when there were entries in the notebook. And it's really starting around April 20th and moving forward.

You can see it in both our demonstratives that you have and look back at their listing as well.

We looked just at business days. We didn't try to count holidays or weekends and looked for days where there were no laboratory notebook entries.

Now, this period of time, whether you start April 1st, May 1st, pick the dates in there, it's after the death of Dr. Selinsky's father. That's not an issue. The main excuse item within that is the period spent on the dissertation and about a week spent polishing up the article that was published as the May 1998 Selinsky paper.

And we did, in our opposition, raise the question with multiple inventors and one Dr. Howell, who seems to have been the lead inventor.

In fact, Dr. Selinsky emerges as in some respects the pair of hands who was trying to reduce to practice for the ultimate mind from which the concept sprung to begin with, Inventor Howell. He's a professor. He's got a whole group of students. She was one of them. There is never an explanation why he didn't choose to give assignments to others when she wasn't available.

The Kitamura (phonetic) case seemed rather on point in that regard where you had a professor try to excuse because he was waiting to the next budget cycle when you get a new graduate student rather than shifting some work to a current graduate student.

It's that notion of just relying upon Selinsky when there were other hands, the people who had done the experiments that supposedly proved out the concept were still around. Why wasn't anybody else working?

There was also no showing that Selinsky was up against a

critical time period when she had to get the thesis or dissertation done by then or she was going to go past a critical deadline. Sure, there are a number of missing elements, we think, in trying to rely upon that as excuse time.

The laboratory notebook also has some entries for work on research that we've given you citations to the deposition testimony which show that work wasn't really directed towards the invention. That's not even addressed in that 144 days. Those would be more days that come off the board as having been actively working on this invention.

JUDGE TIERNEY: So for purposes of viewing Howell's motion, does it make any difference whether we use the April 1st date or the May 21st date?

MS. CAHOON: I don't think it ultimately does. There are huge gaps.

JUDGE TIERNEY: So for purposes of today, we could just give them the May 21st date and hear what they have to say and just simply --

MS. CAHOON: I think they would still fall woefully short if we did that, Your Honor. Because if you look at either our demonstrative or their own charting, it may change the percentage slightly.

It's still going to be 20 percent or more of the workdays unaccounted for before taking into account any of the other issues we raise about experiments by their own admission weren't really directed towards reducing this invention to practice but related to something else.

Doesn't take into account the arguments that we raised that they went about this in a way more focused on commercializing and trying to have enough antibody to use in a column for a human, which is where you have all these large quantities of blood instead of taking an available

commercial antibody that they used in the earlier experiments and working through a murine model or something that was less demanding and less costly.

When they raised the cost burden, which is their explanation for this, the cases again say they have a burden to explain what the costs were, what the comparisons were, what was their availability of funds. There is nothing in the record where they have sought to do that in their motion papers here or even in their response.

There is also then the question of the fact that if you look at their calendar or our demonstratives from July 1, '99, which is when Howell says that the patent application was first given to the patent attorney through the actual filing on November 20th, there are many days that we generally shade as gray on our chart indicating there is no scientific activity going on.

So what they have is a period of almost five months between July 1st and November 20th when whatever diligence there is primarily comes from the patent application process.

Yet there we have a patent lawyer who provided no real evidence of diligence, didn't have the daily time entries which often are provided -- I'm not saying they are absolute requirements, but they certainly weren't provided -- didn't have any indication of what other work pressures were there that might cause prioritization of work to make her incapable of giving more attention to getting this application filed.

And really at the end of the day no explanation as to why it took almost five months between having a draft application and an actual filing.

Again, in the cases we've cited in our opposition papers, periods of substantially less than that have been deemed not demonstrative of

diligence. And periods only slightly longer were clearly outside the bounds of diligence.

So again, another major hole in the proof by the party that had the burden of proof on this issue. So whatever date is the appropriate to start with, I think if you look at what Howell presented to support the claim of diligence, it's very thin.

Frankly, to me, if this panel were to conclude that he had demonstrated diligence, it would be pushing the envelope on the cases on all of these kinds of issues, the sort of diligence showing of the lawyer, the number of days when you can do nothing, the burden of showing if you rely on a cost justification for not doing something, what it was, the efficiency issue and the way you go about a reduction.

To me this is not a case where the inventors have made prima facie showing as junior party of real diligence over a protracted period of time whether you start the clock in early April or you start it May 20th or 21st.

If there are other questions, I'll be happy to respond to them.

JUDGE LANE: Just one thing before you sit down. On this inequitable conduct issue, has that been fully briefed?

MS. CAHOON: No. The way that entered the case, I looked back to see where is the briefing on that.

And in the Howell opposition to Lentz motion one which was seeking to amend the claims in interference and the substitute claims, among the arguments made in response by Howell was a suggestion that this amendment really shouldn't be allowed because there was inequitable conduct in prosecuting the underlying applications for which this one was dependent for its priority claim and therefore it would be infectious in

validity and unenforceability affecting any amendment.

So it's sort of a futility argument due to inequitable conduct.

At that time the argument was based solely upon two references, a 1990 article in a Japanese journal of apheresis that Dr. Lentz had published and a 1997, I believe it was, review article of Dr. Lentz which was addressed in the response with declarations from scientists indicating the cumulative nature of those references which have been considered in some forums and none of which have ever resulted in the rejection of claims of the earlier patents.

And even though presumably Dr. Howell knew then of this alleged giving of the manuscript and its criticality in showing that Lentz had done something wrong in prosecuting when he swore behind the Selinsky article date, there was no mention of that until these much more recent motions as we've entered the priority phase.

So there was a response filed. There was a conference. And at that time in -- I've got the paper number over there -- Your Honor indicated -- actually, what happened, it was a motion after the response was made. Howell moved for a right to surreply to address the response that included a response on inequitable conduct.

The court ultimately determined that wasn't appropriate and any issues about inequitable conduct could be deferred and the Board would ultimately determine whether there would be a phase in which a motion could our should be presented on that issue.

JUDGE LANE: Wasn't Howell also asking to cross-examine Ms. Pabst?

MS. CAHOON: That was being raised at that time, too, yes.

JUDGE LANE: And then later on Howell was -- after the

hearing on preliminary motions, Howell was authorized to file a motion attacking the Lentz claims, the original Lentz claims because the amended claims were not allowed in, right, over prior art?

And as I recall, then there was a call where Howell also asked to raise this inequitable conduct issue again.

MS. CAHOON: And that was -- I believe that call came in the context of the priority briefing issues and this question of should Jennifer Lentz be deposed and would she say something that would be dramatically helpful to his case.

JUDGE LANE: I guess what I'm getting down to, in your opinion there hasn't been sufficient briefing already of the inequitable conduct issue?

MS. CAHOON: Well, actually, we believe that there has been.

We responded when the accusation was first raised in a number of the scientific declarations that have been presented about the prior art challenges, which the Board has considered and rejected when these claims were alleged to be obvious or anticipated by certain pieces of prior art, these pieces of prior art were brought into play.

JUDGE LANE: So you feel like you've responded sufficiently in your reply one, I believe it is?

MS. CAHOON: I think we did. And then the record has subsequently, I guess, grown on that point because there has been additional scientific declarations that have gone back and further talked about those same articles and their lack of disclosures that would have made obvious the invention's claim.

But the initial response was there. We've also addressed this whole issue about Jennifer Lentz and the documents, as you may have seen

from the declaration, Mr. Muir, who was accused of being somebody plotting to steal Dr. Howell's, et al.'s, invention. He's denied it.

He's also shown what Ms. Lentz contemporaneously was saying about Dr. Howell, which was far from flattering, and suggested if any intellectual property thievery had gone on, it had been Dr. Howell's. Those were her terms. Not mine.

So we don't think that pursuing the deposition of the now-divorced Ms. Lentz is a particularly beneficial step.

And we believe the Board has before it sufficient information to assess whether or not, as we fundamentally said, these other references were merely cumulative and therefore not material references withheld, and secondly, to look at this issue of whether there was anything to suggest that Dr. Lentz either received -- or strong enough evidence that he received the article, and if he did receive the article, is that really a material issue in view of what its contents were?

JUDGE LANE: All right. Thank you.

MR. HUNTINGTON: I'm going to be kind of all over the place because there were various different issues raised, but I'll try to address the various things.

The first is to answer your question, Judge Tierney. I don't see that addressed in our reply. And you are correct, it was raised in the opposition. So I still make my offer, but I understand your point.

With respect to this other application, I don't want to belabor that. I know you'll go and look at the record, but we're not talking about just papers filed now. You can look at the list. Prosecution has been going on repeatedly during that time without the Board ever being informed. You can just look at that.

I want to address specifically, you asked about the fact that there was nothing to show vacation at the particular time in November around Thanksgiving, Christmas.

If you look at Howell Exhibit 2079, which is the declaration of Cheryl Selinsky, she indicates in paragraph 47 that, After finishing my research as a Ph.D. student in mid-September 1998, I began writing my Ph.D. dissertation.

This process involved compiling all of the research that I had conducted while in Dr. Howell's laboratory. The process continued until the dissertation was completed and the oral defense of my Ph.D. dissertation was held in November 1998.

This is a woman who had been working for five years doing research getting her Ph.D. The time period in November up until the beginning of January was a vacation and a well-deserved one. So it may not be on the chart, but it is in evidence here.

JUDGE LANE: Is there any evidence showing that she had to do the dissertation at this time, that it wasn't something she could do at a later time?

MR. HUNTINGTON: In essence -- understand, I only have a bachelor's degree. I don't have a Ph.D. As you know, my wife does, and from what she tells me, you do research until your advisor says you are ready and then you prepare your Ph.D. thesis.

I think that's what happened in this situation. I'm not sure that's necessarily in those words in the record as to whether she could have done it at a different time.

JUDGE TORCZON: We don't have any evidence of the proctor or the dean saying, Your time is running out now.

MR. HUNTINGTON: I don't remember any evidence like that. I mean, her advisor is sitting here, but I don't remember whether it's in his declaration or not. I realize he's not allowed to testify at this proceeding, so I'm not going to ask him.

But I will tell you that basically the way this was done was Dr. Selinsky was given -- Ms. Selinsky, at that time, she was given this project to do and she worked on it throughout this entire time.

And part of the reason why she was only working on it and other people aren't, that's part of the training of getting a Ph.D. is that you take responsibility for a particular project and you do the work on it going forward.

So that's part of the reason why there weren't other people working on this during that time rather than just her doing it. And she did work all the time other than the explanations.

JUDGE TORCZON: The problem we're going to have, though, trying to draft up something that says we buy the diligence case, the problem we're going to face with that approach is that the diligence case is part of the priority showing.

So it's not a question of whether the Howell team gets the patent. It's a question of whether Lentz doesn't get the patent.

And the fact that Howell had good reasons for making a whole bunch of choices, the fact of the matter is, he made choices that dragged the process out and why should Lentz pay the penalty? That's the problem we're going to have to face here, whether we agree with every single individual choice along the way.

MR. HUNTINGTON: Well, yeah, I understand that. And this, I think it brings up the question of the antibodies, making the antibodies

rather than purchasing them.

I mean, my understanding of the whole basis for the interference statute allowing people to do that is that you didn't have to take the most expeditious way to a result. And so you could -- you didn't have to purchase antibodies. You could make them on your own because they just didn't have the resources that a corporation would have.

JUDGE TORCZON: And I accept that point. I guess the problem here is not that any individual choice that Dr. Howell made that was a problem. It's really a question of a cumulative effect. It's not really a question of any individual gap in Selinsky's progress. It's the cumulative effect.

At some point doesn't that balance start to tip -- at some point the balance does tip. How do we write a decision that says, Well, it didn't tip? Given the large number of choices and gaps, how is it that we say, Well, despite all that, Lentz should lose its shot at a patent?

MR. HUNTINGTON: Well, I think the point is that you look at them as excuses. I don't know of any case that says, After you have four excuses or five excuses, then you lose. You need to look at each one of the excuses and say, Is that a reasonable one? If it is, then it shows diligence over the entire time.

I do want to address, though, in that connection, the argument that was made here at the end about two of those times being experiments on other things that are not related to this.

One is the experiments on the enzyme that had caused membrane TNF receptor to cleave and release soluble tumor necrosis factor receptor. That information wasn't included in the application because they weren't able to find that particular enzyme.

If that had been, if they had been able to find it and it was a soluble enzyme, that would have been another inhibitor that they could have removed using the techniques in the application. So it is within the scope of this invention.

And the other one, the GMCSF, where they say it wasn't, if you look at those entries, every single one of those entries says GMCSF and STNFR. So there is no gap there. Yes, there were some other things going on at the same time, but there is not a gap in connection with that.

The gaps that I understand you have to focus on are the ones relating to writing papers, writing dissertations, vacations, et cetera. Those I understand that. But the attack that Dr. Selinsky wasn't working on this, what's ultimately the invention here, that should just fall short.

I want to just say a couple of words about this whole question of whether Dr. Lentz received the Selinsky paper or not. I mean, we've got a mass of stuff here, but the one thing that we don't have is any testimony from Dr. Lentz.

He's the one that should be testifying about this. Not all these other people. It's clear he could have testified. He came here for the deposition of Dr. Howell and doctor -- Mr. Leber and Dr. Selinsky. He was here. He could have testified about it.

You can see that in Lentz Exhibits 1114 and 1115 that show he attend these depositions, and yet he didn't provide a declaration. I think it's reasonable to say the reason that he didn't is because his testimony would have been unfavorable.

JUDGE TORCZON: Let's assume for the sake of argument that we adopt Judge Tierney's suggestion and just spot you guys up to May 21st. Does any of that matter?

MR. HUNTINGTON: Yes, it matters because it matters that Dr. Lentz would not have made this invention without receiving the Selinsky paper.

JUDGE TORCZON: We don't have a derivation motion in front of us. We don't have a derivation motion to grant.

MR. HUNTINGTON: Right. But the reason you don't have a derivation motion to grant is because derivation requires transmitting the entire invention to the other party. It's the Gambro case.

JUDGE TORCZON: I accept the point even without the citation. But I guess my concern is the minute they filed the application, absent an inventorship attack, what we have is a filed application with an oath attached that says Dr. Lentz invented this. We don't have any attack on that. We don't have a motion to grant that says he wasn't the inventor.

MR. HUNTINGTON: Well, perhaps the whole question of receiving the Selinsky paper is something that's more relevant to the inequitable conduct issue than it is to the patentability issue. But I do believe that it's critical information.

You look at, he testifies -- everybody else testifies that from the period of 1990 all the way up through 1997 and even to the first time he met with Patrea Pabst, that he had this idea in the back of his mind but he never puts it down anywhere.

It's only after he gets this paper from Howell that he all of a sudden says, Gee, I should put this in a patent application.

The circumstantial evidence here is very strong. And what do they do? They could have put a declaration in by Dr. Lentz. They didn't do that. They made that choice.

Also, we couldn't find out from Jennifer Camp Lentz whether

this paper was received. They argue vigorously that we shouldn't be allowed to do that. And then what do they do? They give you three e-mails from her without us having a chance to do anything about that because there is no declaration from her.

It's coming in from someone else. They are just continuing to circle around this. And I think the reason is because if you ask Dr. Lentz, I'm not sure what he would say. He certainly didn't want to tell his wife. If you look at --

JUDGE TORCZON: Wait. Before we look at it, you got to understand our selfish preoccupation here is to write a decision on priority. We don't have the inequitable conduct in front of us. We don't have the derivation in front of us. We don't have an inventorship motion in front of us.

So even assuming that all these smoking guns exist, at this point the only thing we really need to know is, how does that change the priority case? I'm not hearing that.

MR. HUNTINGTON: I don't know what else I can tell you. So I'm going to drop --

JUDGE TORCZON: That's a fine answer.

MR. HUNTINGTON: I've said what I want to say. Maybe when you go back and look at this transcript, it will ring with you. But if it doesn't, then it doesn't.

One other thing I want to take up is something that came up as a part of your questioning, Judge Torczon. You were asking about on the one hand they are saying that you could have a constructive reduction to practice. On the other hand, it's not until you have an actual reduction to practice.

I think the case that you were probably thinking about is the Rasmussen case, which is very clear on this point that even if you have a patent application that describes everything, it may not be sufficient to be a constructive reduction to practice.

If people skilled in the art don't -- wouldn't believe what's in the application because it's unpredictable, et cetera --

JUDGE TORCZON: What's Howell's position? Was this sufficiently predictable art or not?

MR. HUNTINGTON: Yes, it was. I think the important thing to see here is the kind of flip-flop on this. On the one hand they want to say, Well, we're entitled to the benefit of this application over here because we had all the information soon enough.

Then on the other hand they want to say, But Selinsky, it's nothing out there because it's so unpredictable; we really didn't know.

In fact, I think you could, based on the admission that they made at page 6, lines 13 through 17 of their opposition, you could find that they hadn't made the invention even when they filed because they say specifically, even with this information it was not possible to predict with a reasonable degree of certainty that the method would work.

It was only later before filing the application in interference, basically in November of 2000. So you could take it as an admission. I'm not sure that it makes sense.

But it would put them at a later time than us because Dr. Howell has consistently maintained that his application was sufficient, whereas they are saying, Well, maybe it wasn't sufficient, and dancing back and forth. So I think it just shows you that their arguments are kind of all over the place.

Let me just take a moment.

JUDGE LANE: While you are thinking, I wanted to ask you about the briefing on inequitable conduct issue. Do you think that that has been fully briefed?

MR. HUNTINGTON: I do not. I don't think it's been fully briefed. And the best explanation I can give is Ms. Cahoon said earlier that experts -- scientific experts had talked about these papers.

I think she's wrong about that unless she's including Ms. Pabst as a scientific expert, because my recollection is the only person who talked about that paper was Ms. Pabst, and we were never allowed to cross-examine her. We certainly at the very least should be able to cross-examine her and provide evidence.

JUDGE LANE: So essentially, if you were permitted to file a surreply to one, that would complete the brief?

MR. HUNTINGTON: I think so, if we were able to take that cross-examination and file a surreply. But understand that as in your order about Jennifer Camp Lentz, the issue of -- the issue of whether this paper was received or not becomes important in terms of statements that were made in a declaration by Dr. Lentz.

Remember, in their prosecution they swore behind the publication date of this paper without ever saying that, Oh, by the way, I knew about it back in February.

If, indeed, he knew about it in February, then he breached his duty of disclosure by not talking about it because it's hard for them to argue that it's not material information when the examiner used it to reject the claims. It's clearly material.

Now, in terms of whether that swear-behind was correct or not,

if he received it in February and he didn't tell the examiner when he filed this 131 declaration, then that's inequitable conduct, assuming intent can be shown.

But with a high degree of materiality, the amount of intent that's required to be shown is pretty low. It's unlikely to show a smoking gun. But you have to wonder why haven't we seen the declaration from Dr. Lentz. We've seen five from Patrea Pabst.

JUDGE LANE: Thank you.

(Whereupon, the proceedings at 11:10 a.m. were concluded.)

CERTIFICATE OF REPORTER

I, Deborah Rinaldo, do hereby certify that the foregoing proceedings were taken by me in stenotype and thereafter reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

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Deborah Rinaldo
Notary Public